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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,773	09/27/2000	Clark Pan	MSB-7272	7437

7590 10/15/2003

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EXAMINER	
MORAN, MARJORIE A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 10/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/671,773	PAN ET AL.	
	Examin r	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 6, 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. All objections and rejections not reiterated below are hereby withdrawn.

Claim Rejections - 35 USC § 102

Claims 1, 6, and 16 are again rejected, as previously set forth in the office action of 2/3/02, under 35 U.S.C. 102(b) as being anticipated by BOLIN (US 5,234,907).

Applicant's arguments filed 8/6/03 have been fully considered but they are not persuasive. In response to the argument that BOLIN does not teach or disclose SEQ ID NO: 72, it is noted that the claims do not recite a polypeptide consisting of SEQ ID NO: 72. The instant claims are directed, as admitted by applicant on page 3 of the response, to "functionally equivalent fragments, derivatives, and variants" of a recited SEQ ID NO. The examiner does not interpret a polypeptide "represented by" SEQ ID NO: 72, as recited in claim 16, to be a polypeptide consisting of SEQ ID NO: 72. The examiner interprets claim 16 to be limiting the SEQ ID NO: to a single one of the list recited in claim 1 (i.e. claim 16 is interpreted to be directed to a fragment, derivative, or variant of SEQ ID NO: 72).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the mutations listed on page 3 of the response, a polypeptide which is a selective R3 agonist) are not recited in the rejected claim(s). Although the

claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The specification teaches, on page 11, paragraph 57, that a "variant" is one a sequence with "sufficient similarity" to one of those disclosed, and teaches that "sufficient similarity" is defined as at least about 45% , or from 75% through 98% sequence identity. It is noted that BOLIN's SEQ ID NO: 1 (at least) is over 77% identical to instant SEQ ID NO: 72.

With regard to functional "similarity", it is noted that the instant specification teaches on page 7 that VIP is a peptide known to stimulate insulin release. Page 8 of the instant specification teaches that some of the inventive peptides also cause stimulation of insulin release in a glucose dependent manner. SEQ ID NO: 72 is among those listed which are disclosed to have this activity. As BOLIN teaches that his peptides have activity similar to that of VIP, and the instant specification teaches that SEQ ID NO: 72 has activity similar to VIP, the examiner maintains that BOLIN's peptides are "functionally equivalent variants" of SEQ ID NO: 72, and maintains the rejection.

Claims 1, 6, and 16 are again rejected, as previously set forth in the office action of 2/3/02, under 35 U.S.C. 102(b) as being anticipated by SAWAI et al. (US 5,376,637).

Applicant's arguments filed 8/6/03 have been fully considered but they are not persuasive. In response to the argument that BOLIN does not teach or

disclose SEQ ID NO: 72, it is noted that the claims do not recite a polypeptide consisting of SEQ ID NO: 72. The instant claims are directed, as admitted by applicant on page 3 of the response, to "functionally equivalent fragments, derivatives, and variants" of a recited SEQ ID NO. The examiner does not interpret a polypeptide "represented by" SEQ ID NO: 72, as recited in claim 16, to be a polypeptide consisting of SEQ ID NO: 72. The examiner interprets claim 16 to be limiting the SEQ ID NO: to a single one of the list recited in claim 1 (i.e. claim 16 is interpreted to be directed to a fragment, derivative, or variant of SEQ ID NO: 72).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., an analogue in which the amino acid at position 17 has been mutated, polypeptides which are selective R3 agonists) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The specification teaches, on page 11, paragraph 57, that a "variant" is one a sequence with "sufficient similarity" to one of those disclosed, and teaches that "sufficient similarity" is defined as at least about 45% , or from 75% through 98% sequence identity. It is noted that SAWAI's sequence is over 77% identical to instant SEQ ID NO: 72.

With regard to functional "similarity", it is noted that the instant specification teaches on page 7 that VIP is a peptide known to stimulate insulin

release. Page 8 of the instant specification teaches that some of the inventive peptides also cause stimulation of insulin release in a glucose dependent manner. SEQ ID NO: 72 is among those listed which are disclosed to have this activity. As SAWAI teaches that his peptides have activity similar to that of VIP, and the instant specification teaches that SEQ ID NO: 72 has activity similar to VIP, the examiner maintains that SAWAI's peptides are "functionally equivalent variants" of SEQ ID NO: 72, and maintains the rejection.

Conclusion

Claims 1, 6, and 16 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number

is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN
PATENT EXAMINER

Marjorie A. Moran

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